Carotid Artery Stent Fractures: An Engineer's Perspective

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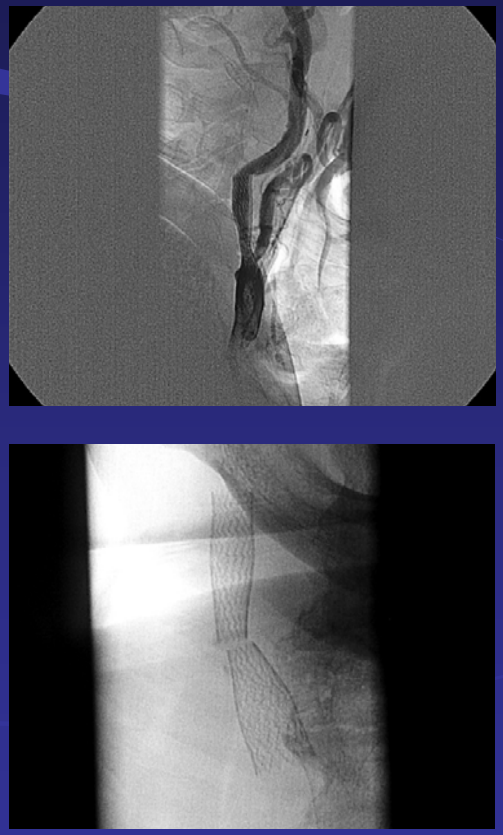
Affiliation and Disclaimer

- ECHOBIO LLC provides engineering analysis and expert services to clients in the medical device industry. Dr. Perry and ECHOBIO LLC do not have any financial interests related to carotid stents or stent products.
- The data contained in this presentation is provided for illustrative purposes only.

  Specifically:
  - Device architecture and geometry data does not represent any commercially available product.
  - Boundary condition data does not specifically reflect recommended parameters to be used for evaluating a device
  - Material limit data are not generally applicable to other cases

Survey of Carotid Artery Stent Fractures

- Fracture of a carotid artery stent: An unexpected complication, Valibhoy, et.al, *Journal of Vascular Surgery*, March 2007
  - Confirmed fracture within <6 months
- Carotid in-stent restonosis associated with stent fracture and migration, N'Dandu et.al, *Cardiovascular Revascularization Medicine* 7, 2006
  - Confirmed fracture within <6 months
- Stent Fracture After Endoluminal Repair of a Carotid Artery Pseudoaneurysm, de Vries *Journal of Endovascular Therapy* Volume 12, Issue 5, 2005
  - Confirmed fracture within <7 months

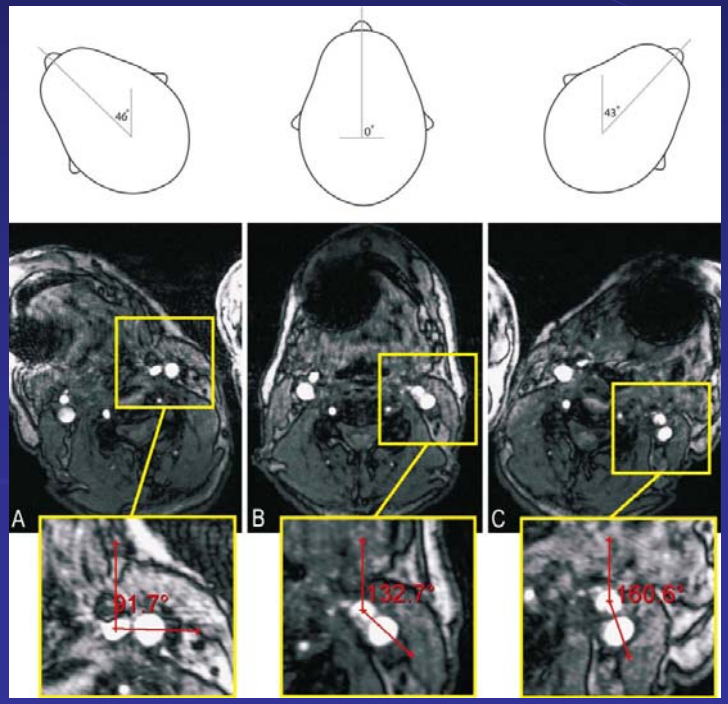


Valibhoy, et.al, *Journal of Vascular Surgery*, March 2007

Mechanical Challenges for Carotid Artery Stents

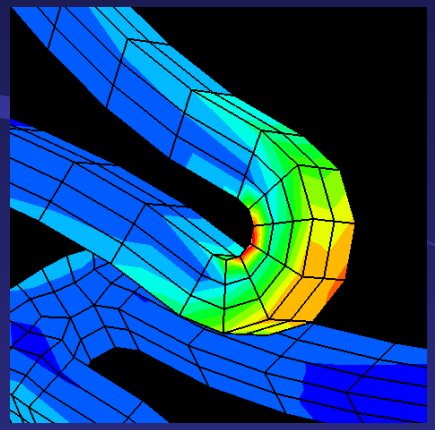
- Anatomical considerations
  - Geometric tortuosity - bifurcations
  - Stiffness gradients - calcification
- Motion and deformations
  - Twist due to head movement
  - Axial stretching and bending
- Deployment considerations
  - Axial stretching/twisting
  - Multiple overlapping stents

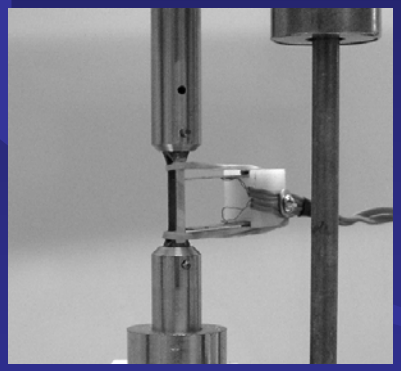
Vos et.al., Endovasc Ther, 2003

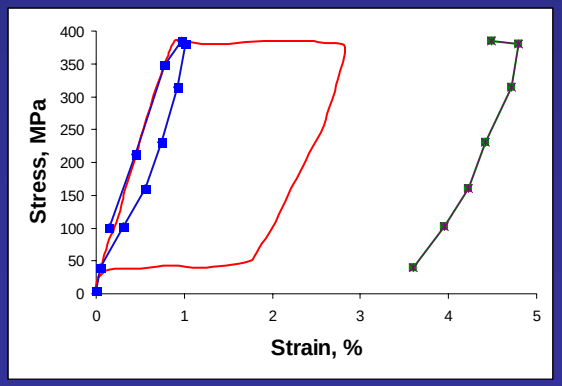


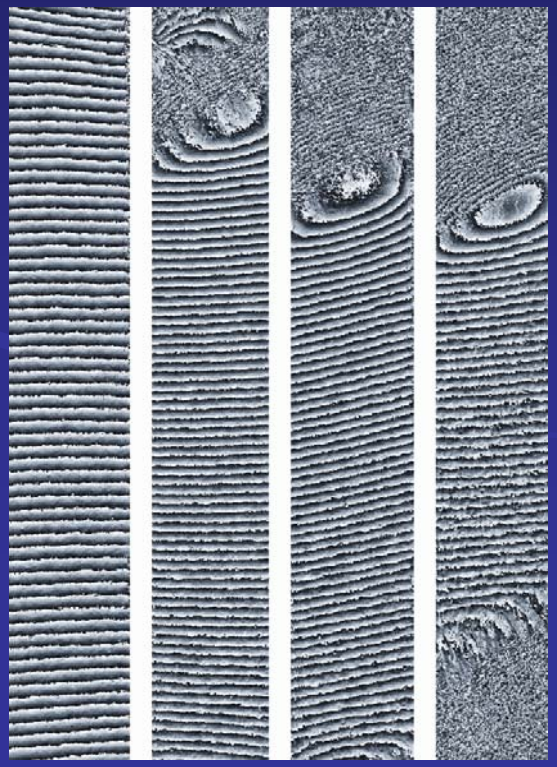
Nitinol Material Behavior

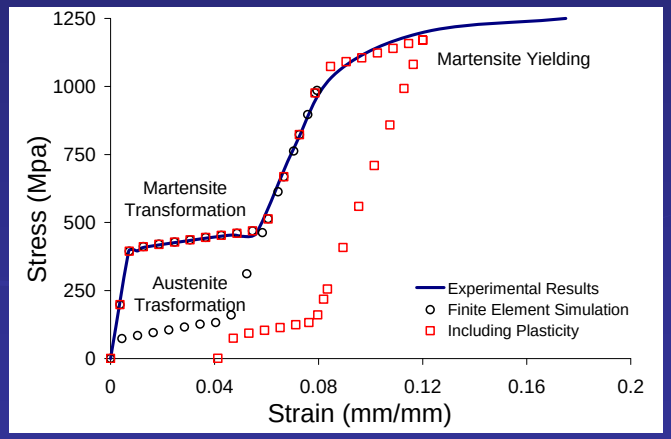
- Superelastic material behavior
  - Large recoverable deformations
  - Two phase material response
  - Retained martensite, local plasticity









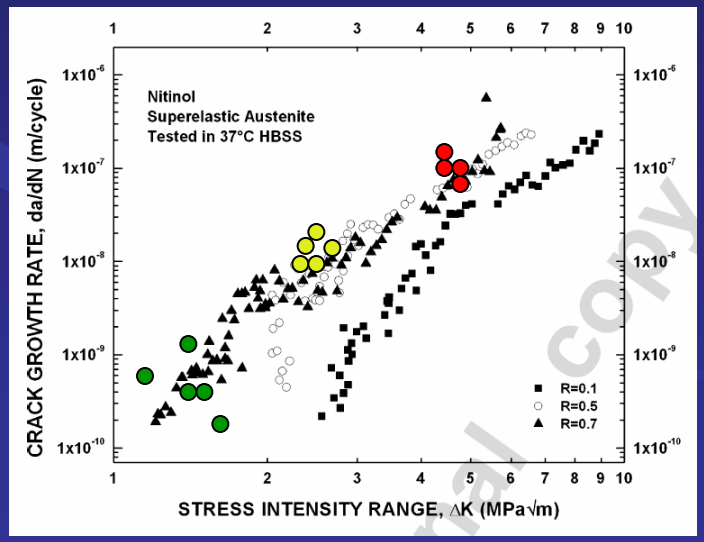


Perry et al., ASM, 2005

Perry et al., Journal of ASTM International, Vol. 3, No. 9, 2006

Nitinol Fracture and Fatigue

- Traditional LEFM, EPFM are not applicable to medical devices
  - Small features (~100 microns)
  - Two phase material



McKelvey and Ritchie., J. Biomed. Mater. Res. 1999

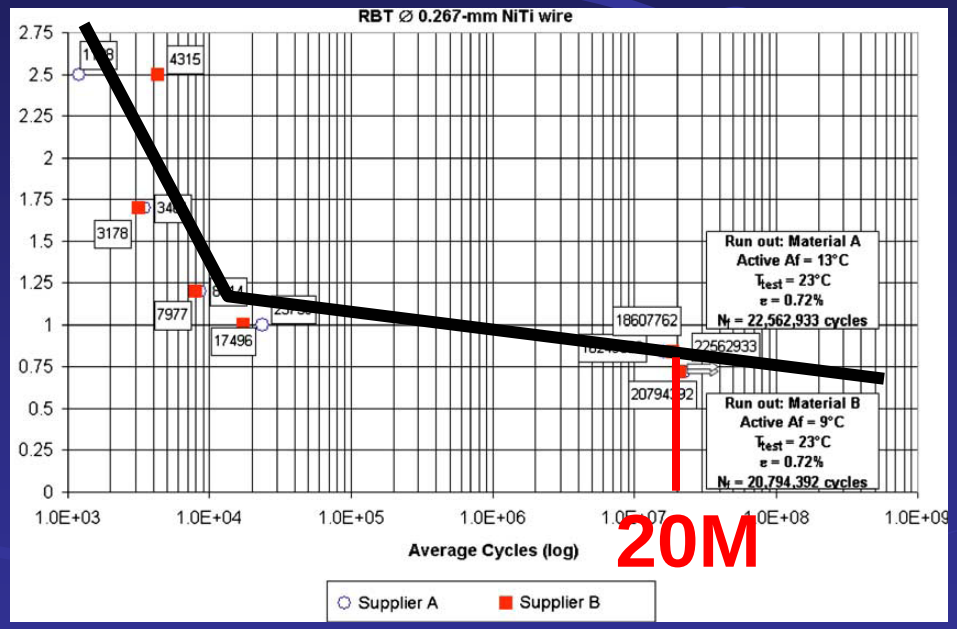
R=0.50
R=0.25
R=0.90

Perry et al., SEM, 2007

- Crack initiation more relevant to material limit characterization and development

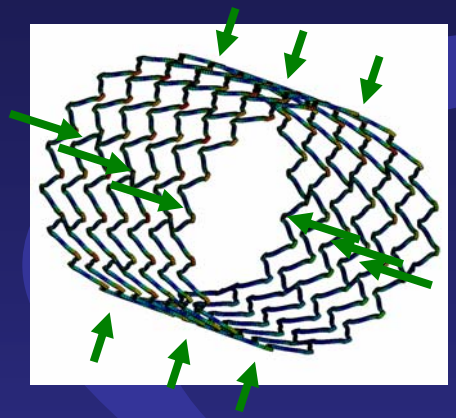
Material Limit Data for Nitinol

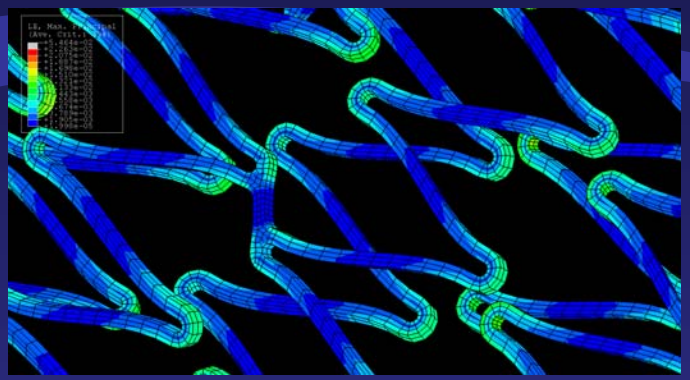
- Configuration specific (wire, tubing, sheet, etc)
- Processing effects
- Loading mode (tension, compression, bending, torsion, etc)
- Mean strain effects
- Test efficiency and statistics
- FEA to correlate deflection/strain

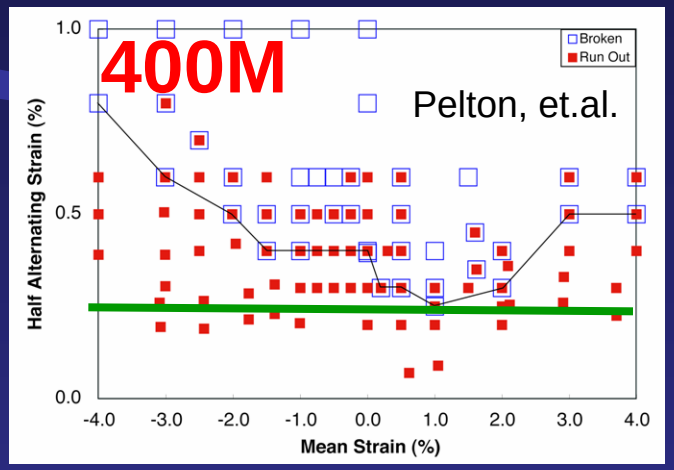


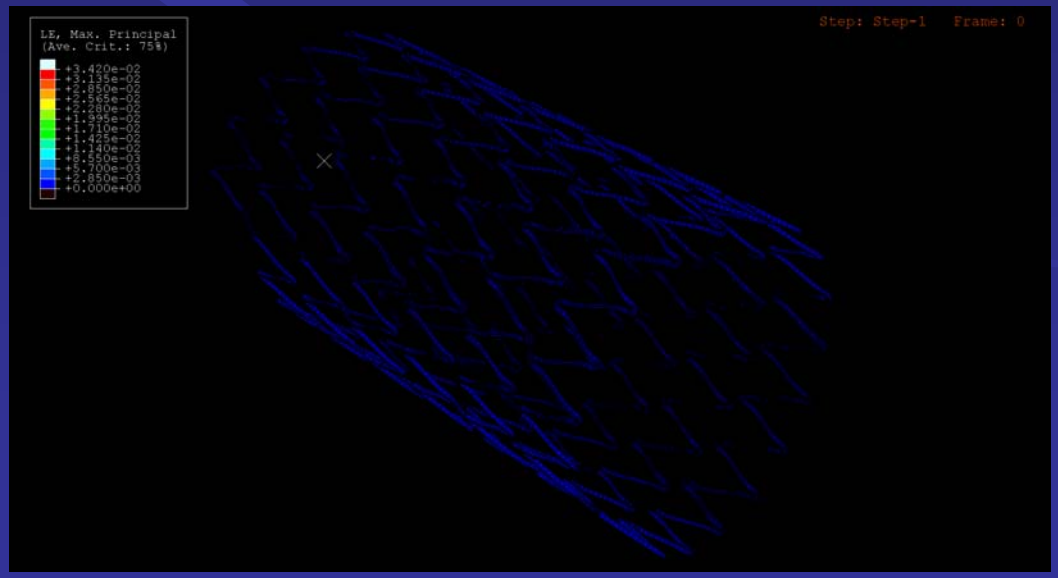
Patel M, Journal of ASTM International, Vol. 4, No. 6, 2007

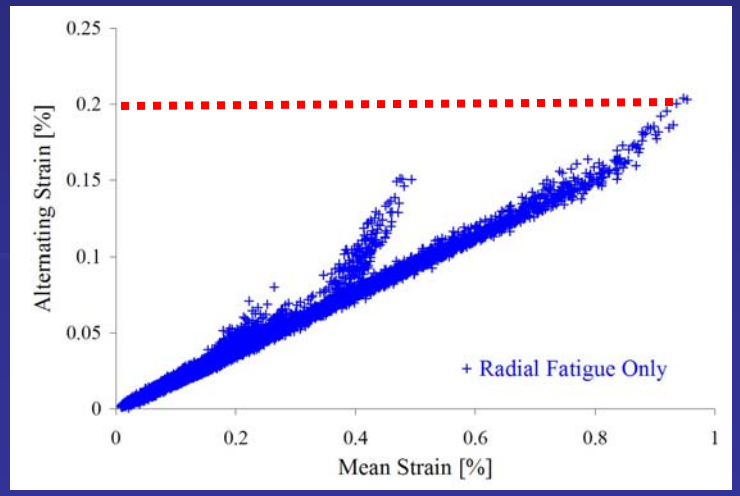
Uniform Radial Fatigue



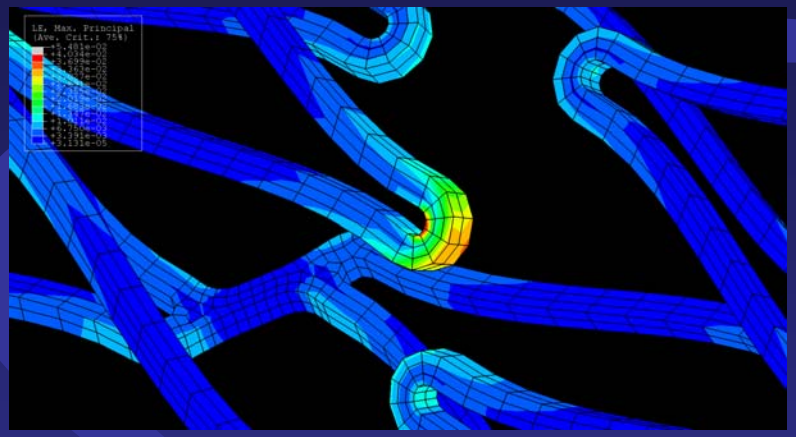


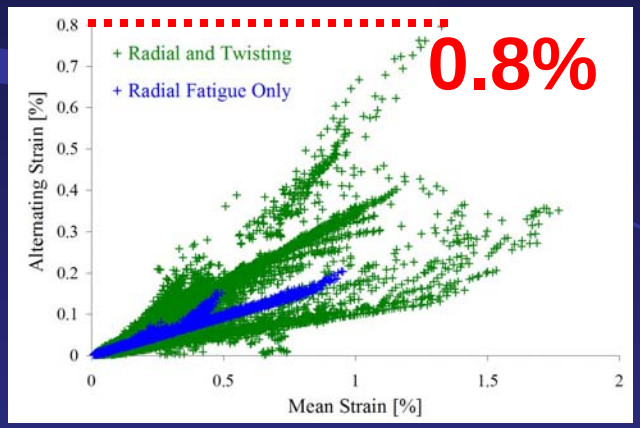


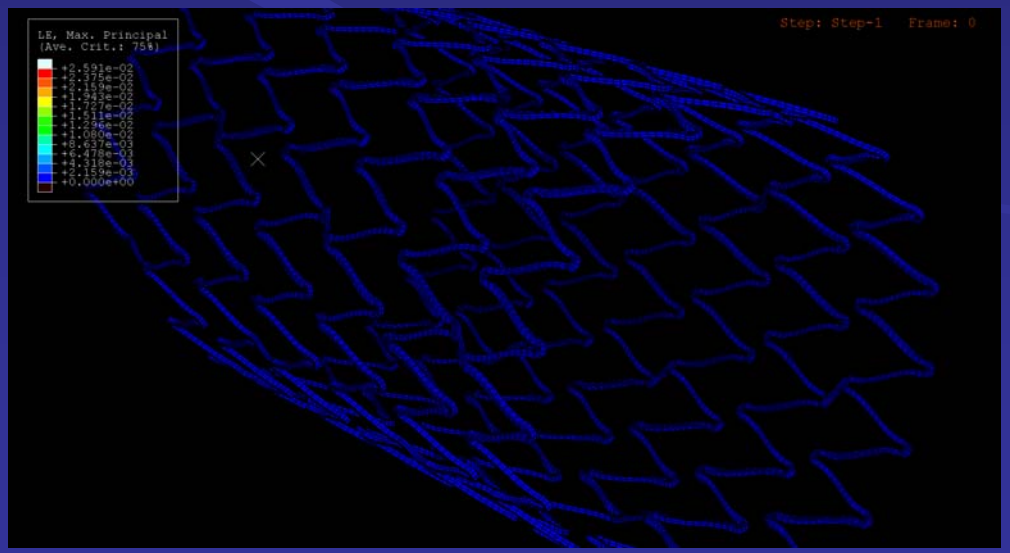


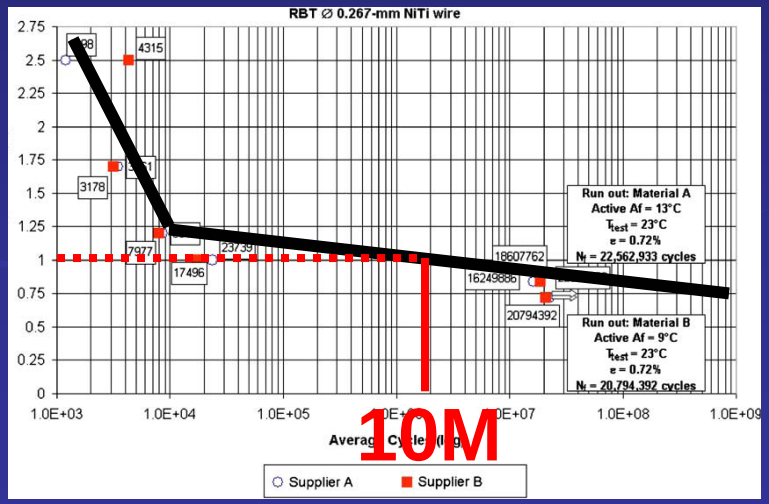


Coupled Deformation Modes

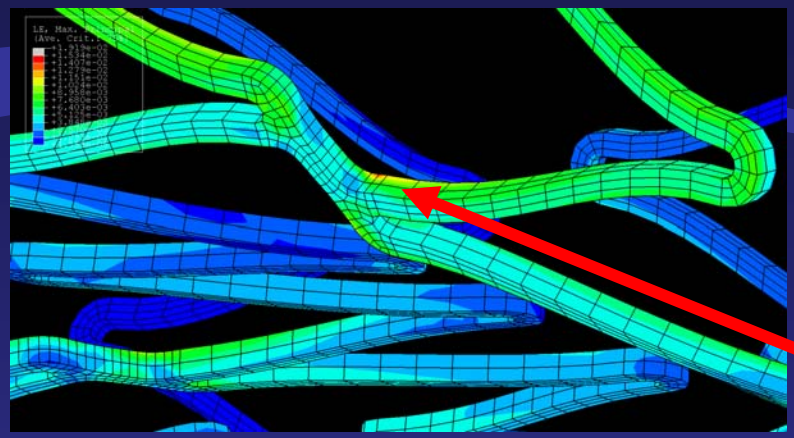








Crushing Deformation



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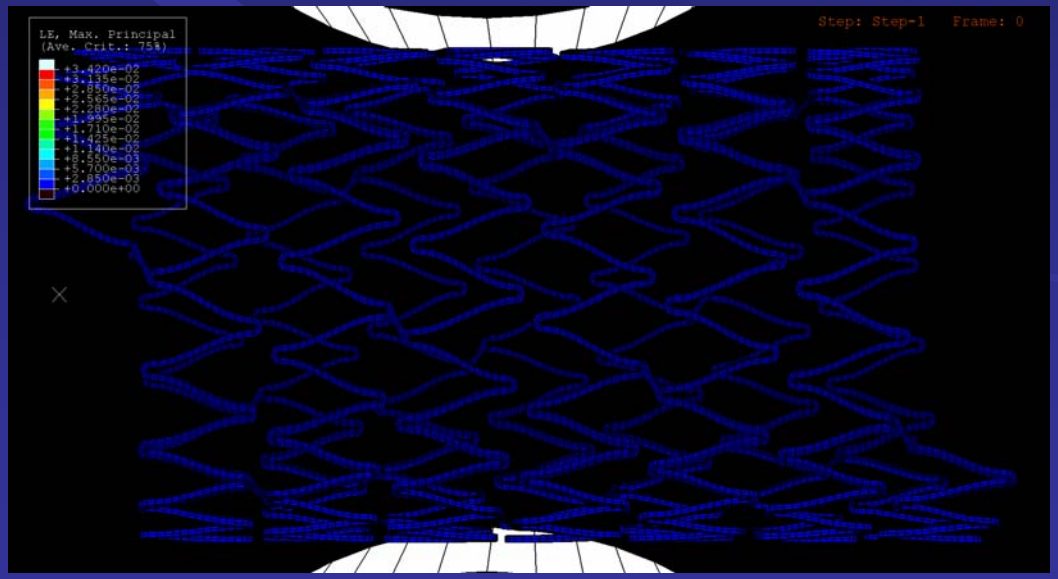

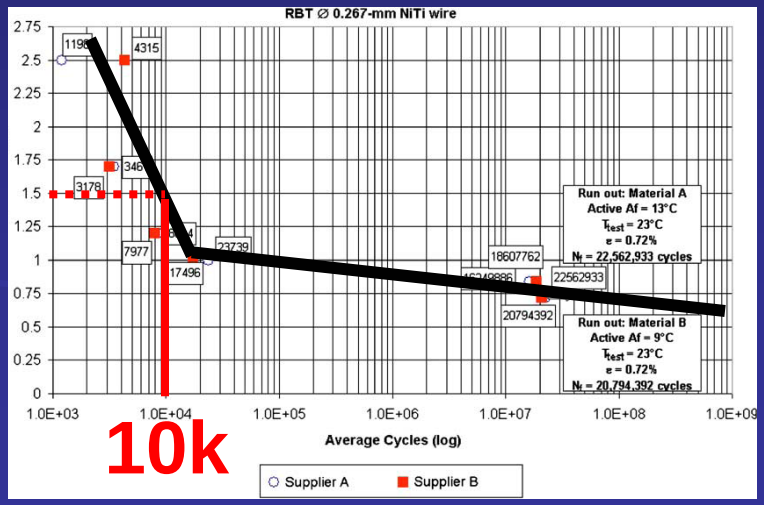

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design engineering analysis

Evaluation of Total Fatigue Life

Load Case	Anticipated Design Cycles	Alternating Strain Limit	Alternating Strain Predicted	Safety Factor
Radial Fatigue	400M	0.40	0.20	2.00
Twisting Fatigue	10M	1.00	0.70	1.40
Radial and Twist	10M	1.00	0.80	1.25
Crushing	10k	1.50	1.30	1.15

Loading modes may be coupled…

Each fatigue mode will consume some portion of the Total Fatigue Life. Need to consider combinations…

Summary

- Testing to 400M cycles with pulsatile radial loading does not adequately address stent fractures seen clinically
- Comprehensive engineering methodology required to optimize and validate stent designs for the carotid arteries
  - Medical imaging measurement and analysis to define clinically relevant deformations
  - Testing to failure to provide feedback for material limit data and component durability
  - Computer simulations to evaluate impact of deformations against established material limits